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Stolz et al.

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(54) **IMPLANTABLE LEAD WITH ISOLATED CONTACT COUPLING**

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(74) *Attorney, Agent, or Firm*—Fredrikson & Byron, P.A.

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(57) **ABSTRACT**

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(58) **Field of Classification Search** 607/117, 607/116, 115, 122, 123, 37; 600/372, 373, 600/374, 393; 439/909

See application file for complete search history.

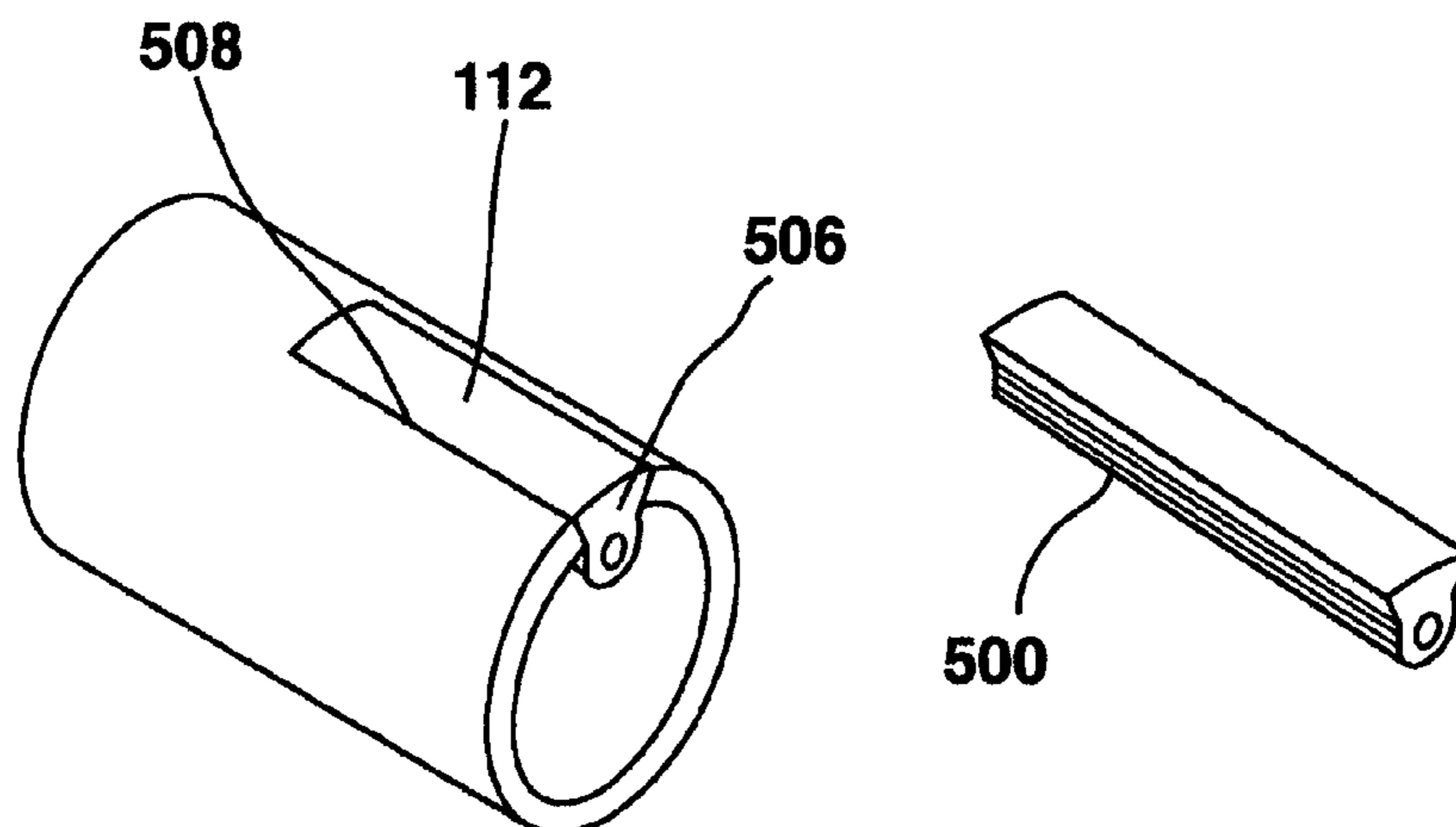
An implantable lead for a medical device with an isolated contact connection for connecting a conductor to a contact reduces the opportunity for conductor material to migrate to a contact or into a patient. The implantable lead comprises a lead body having a proximal end and a distal end, at least one conductor, at least one contact carried on the proximal end, at least one contact carried on the distal end, at least one coupling. The lead has an exterior surface. The conductor is contained in the lead body and extends from the lead proximal end to the distal end. The conductor is electrically insulated. The contact carried on the proximal end is electrically connected to the conductor. The coupling has a conductor coupling and a contact coupling. The conductor coupling is placed over the conductor and attached to the conductor. The contact coupling exits the lead body and has a weld to connect the contact coupling to the contact. There is an isolation space created between the conductor and the contact to prevent the weld from containing conductor material.

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18 Claims, 11 Drawing Sheets



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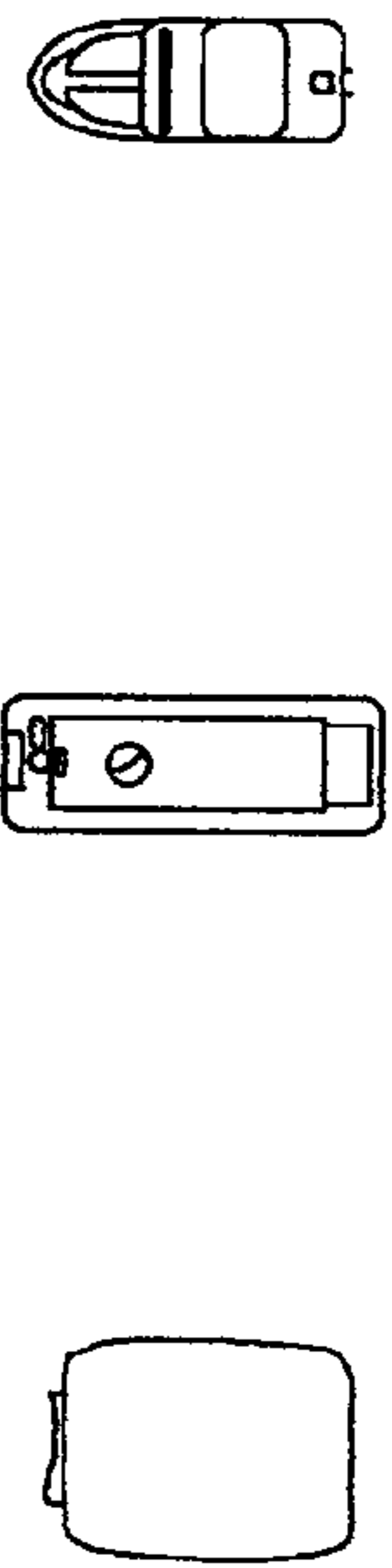
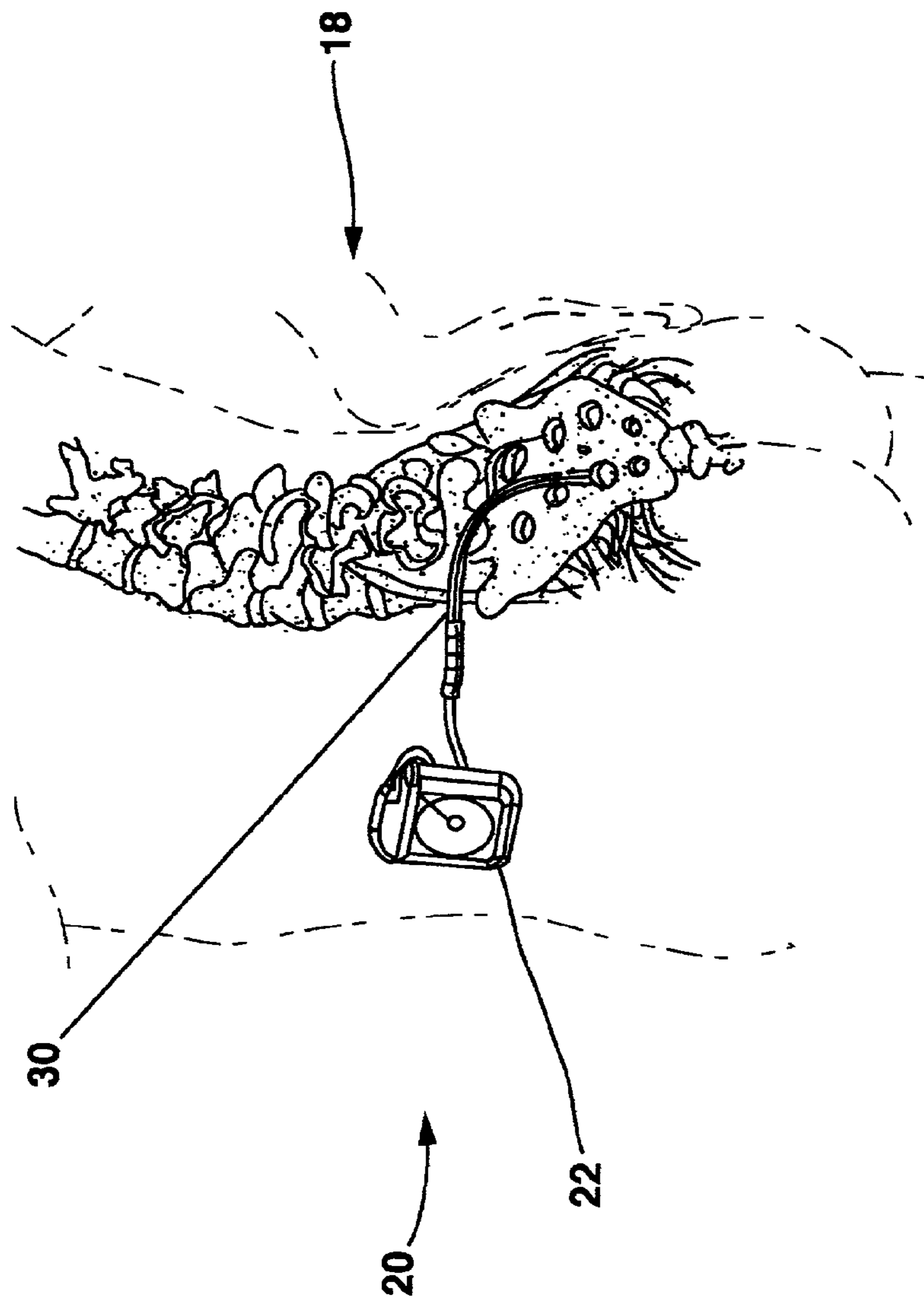


FIG. 1

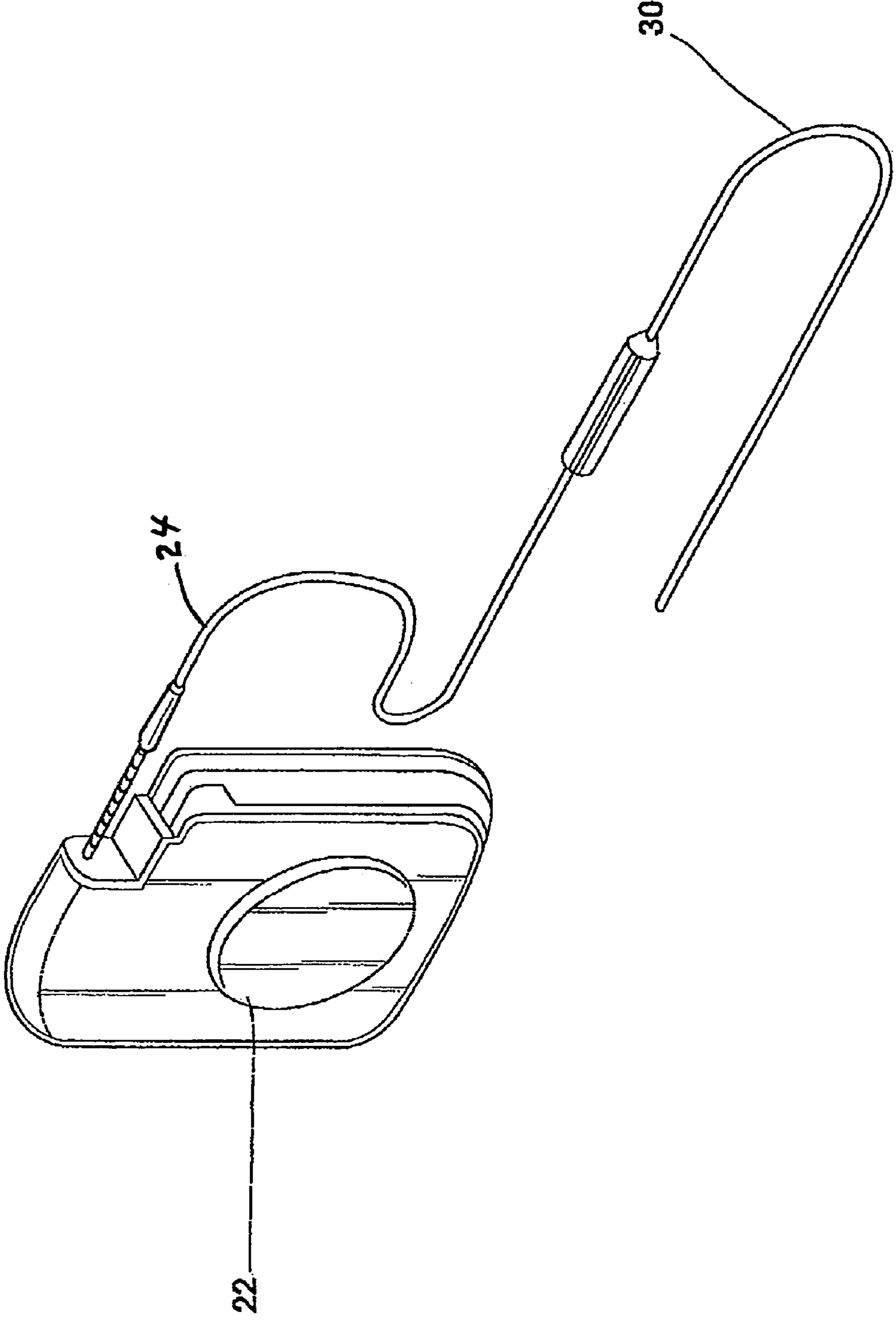


FIG. 2

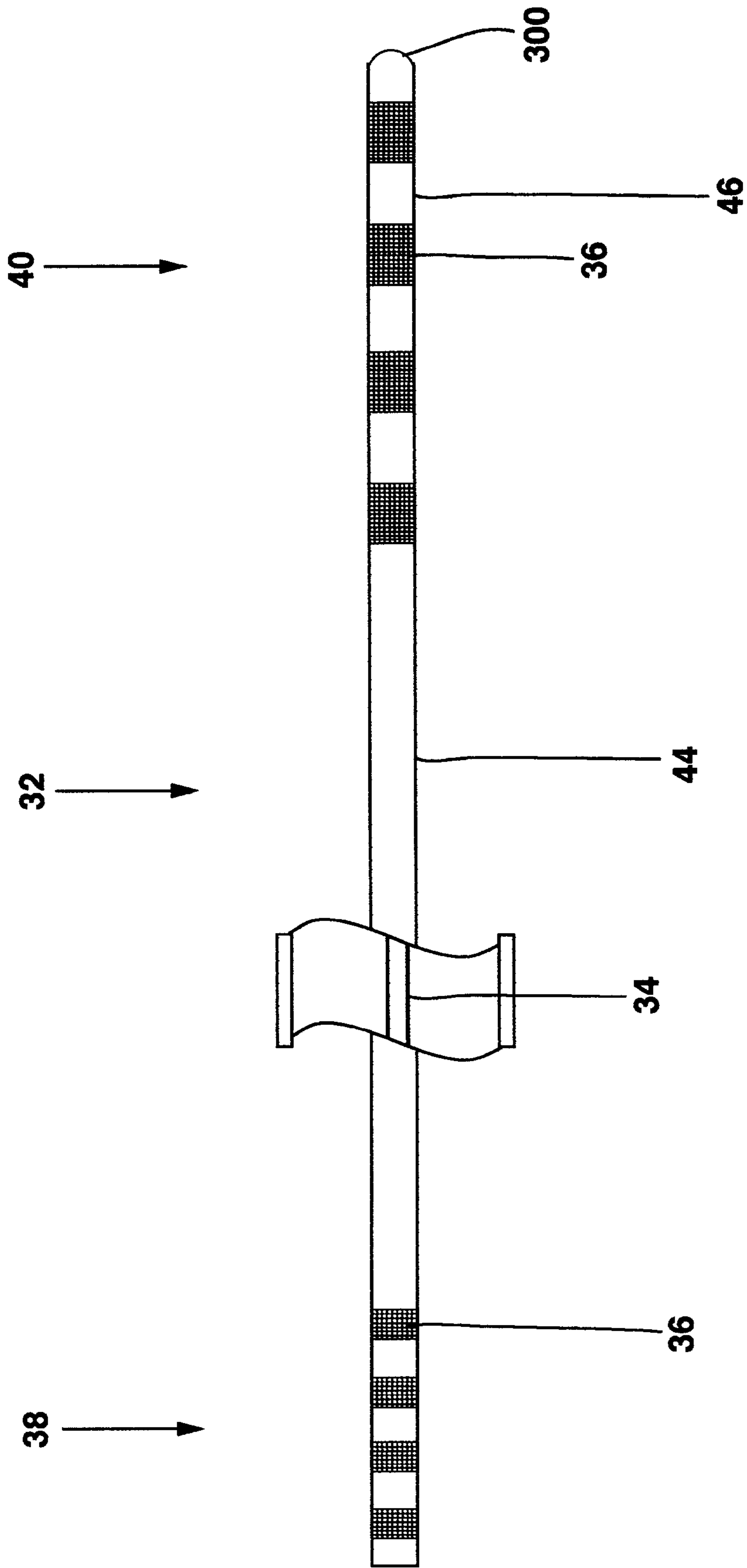
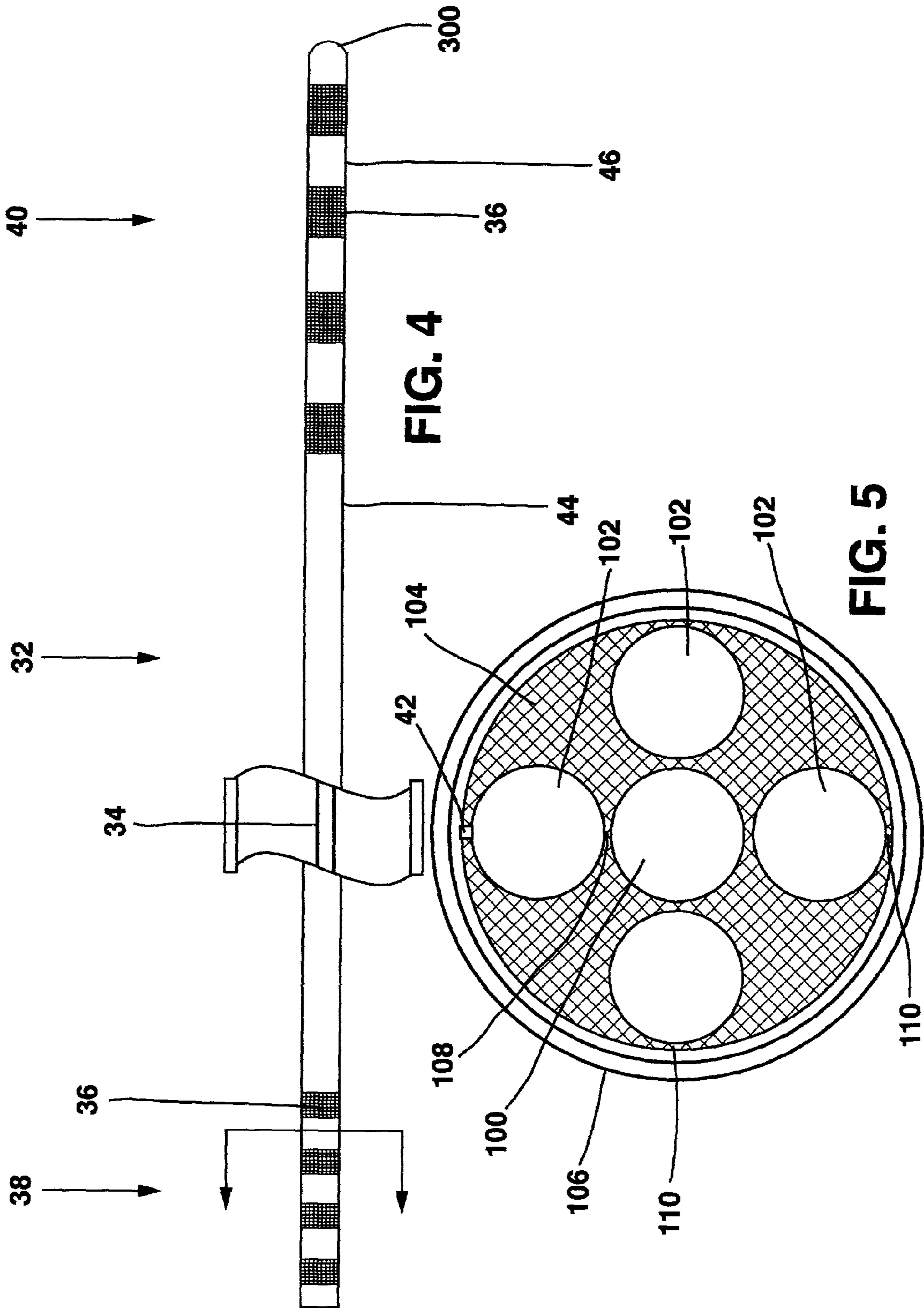


FIG. 3



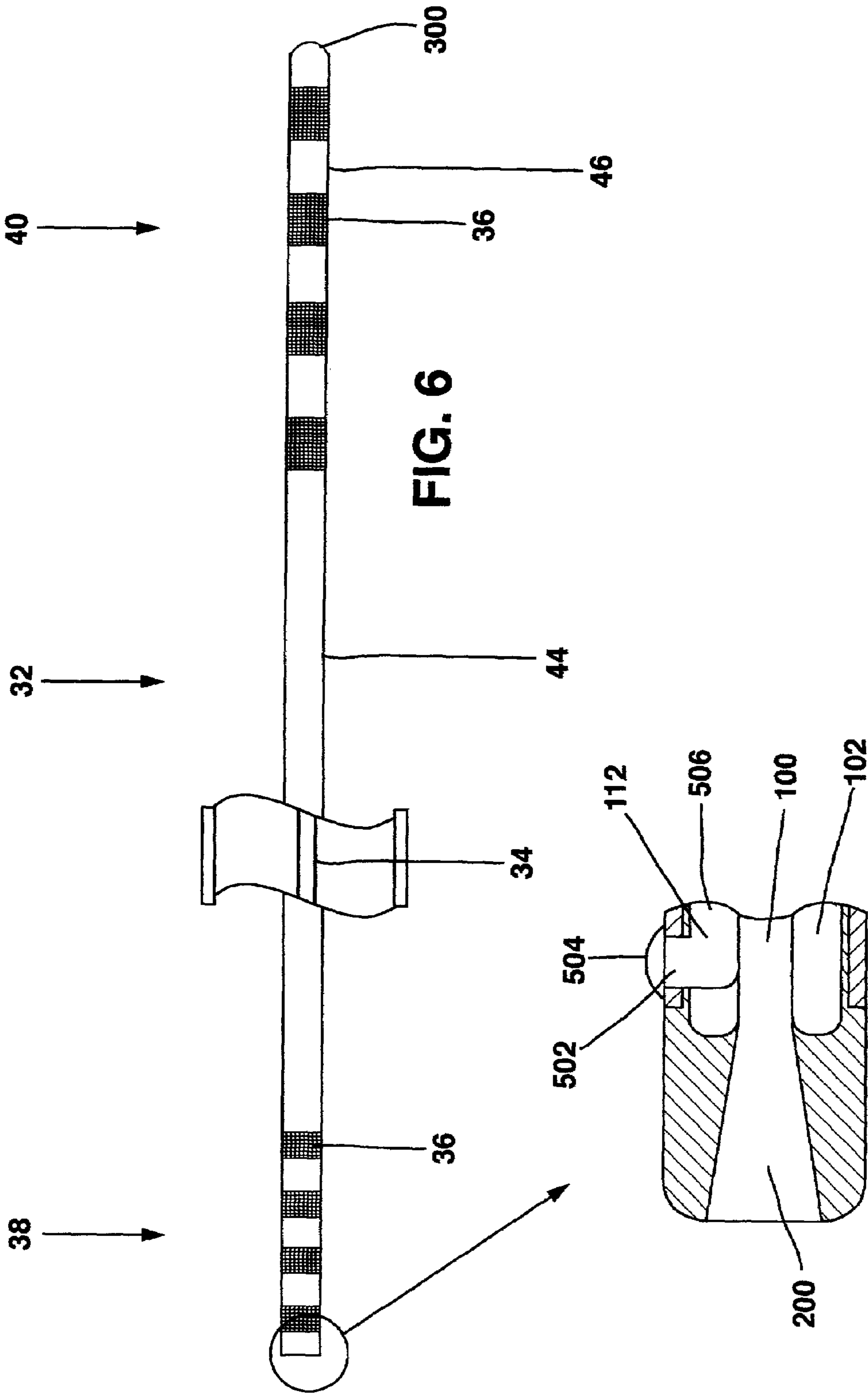


FIG. 6

FIG. 7

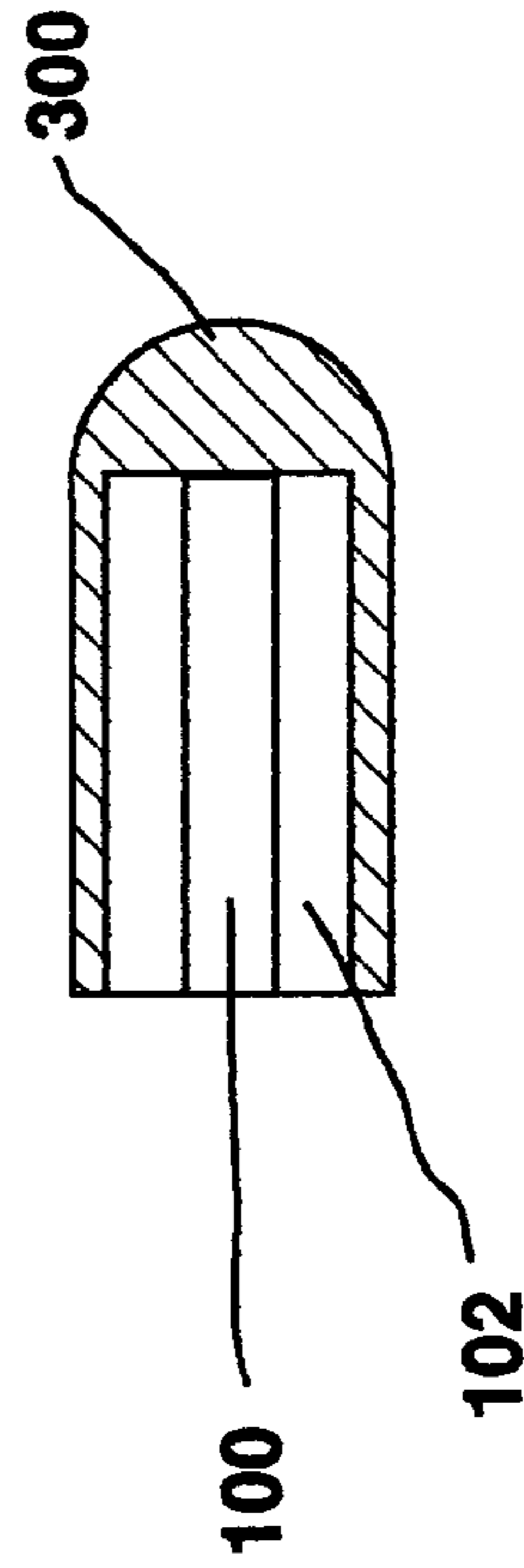
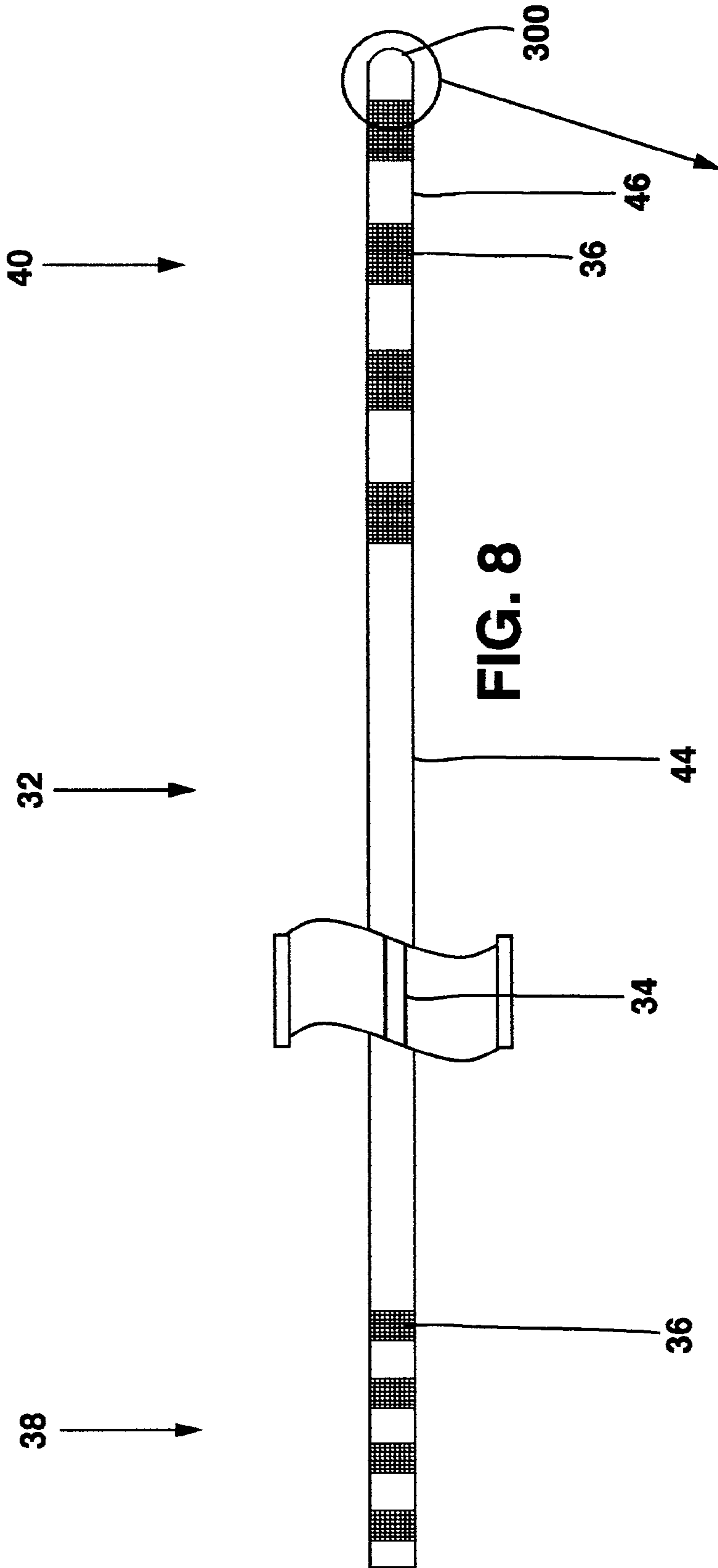


FIG. 9

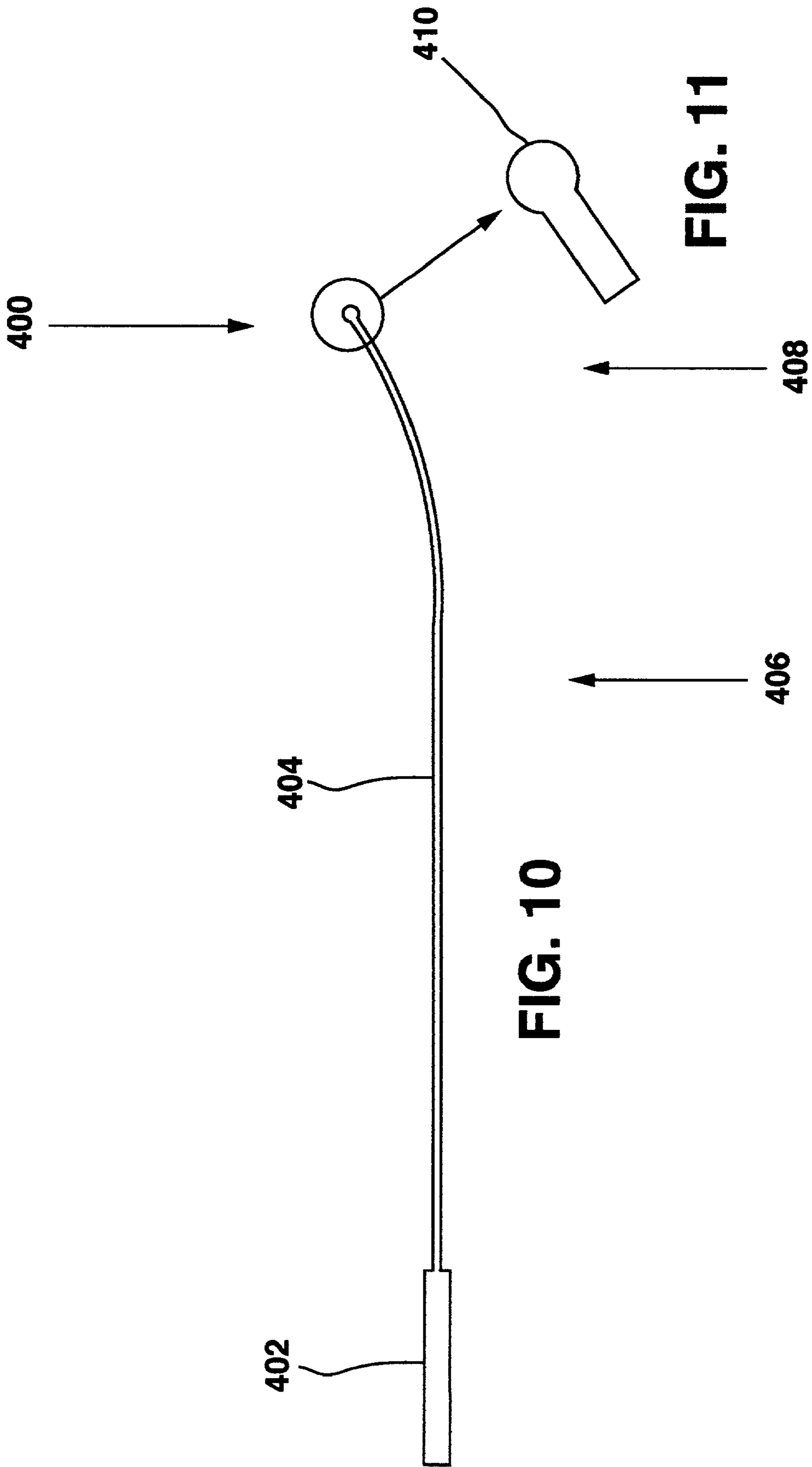


FIG. 10

FIG. 11

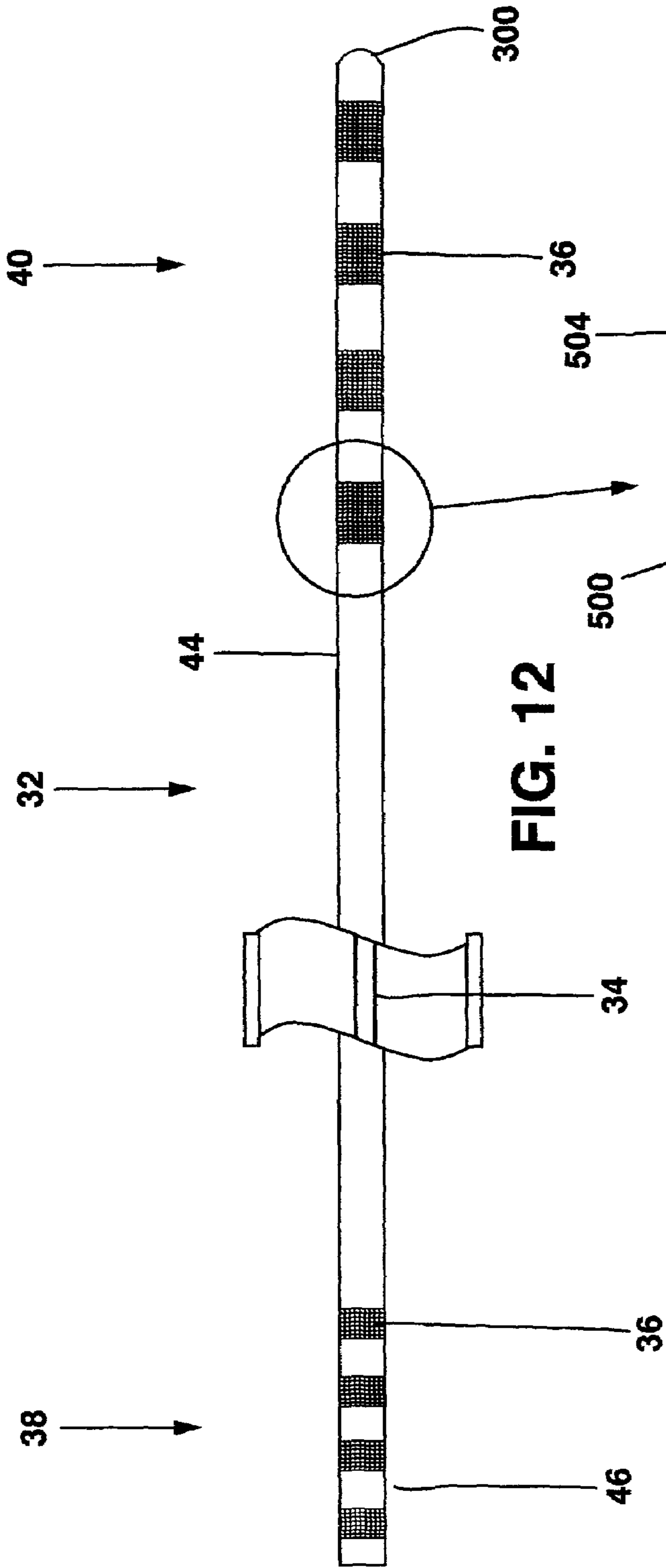


FIG. 12

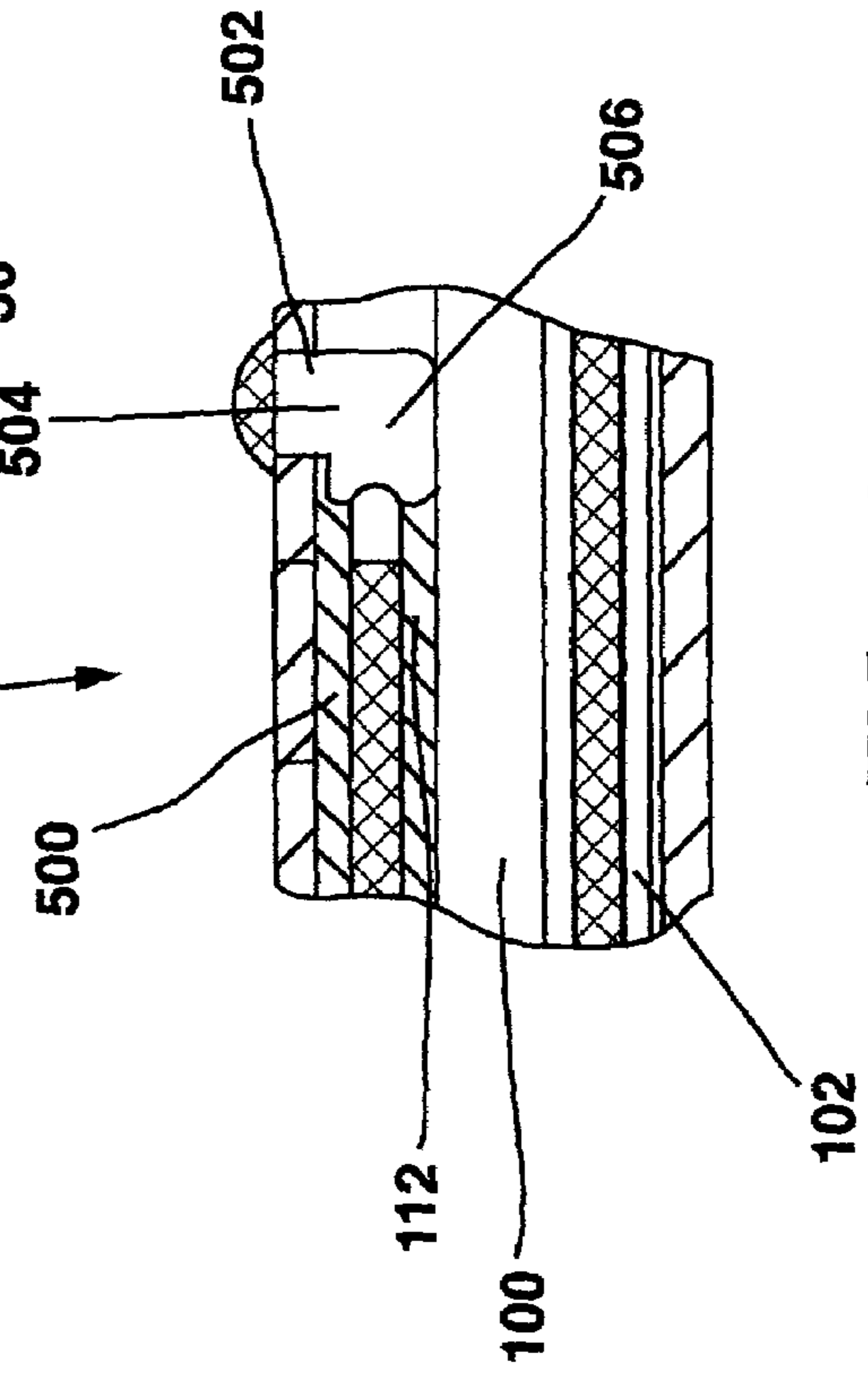


FIG. 13

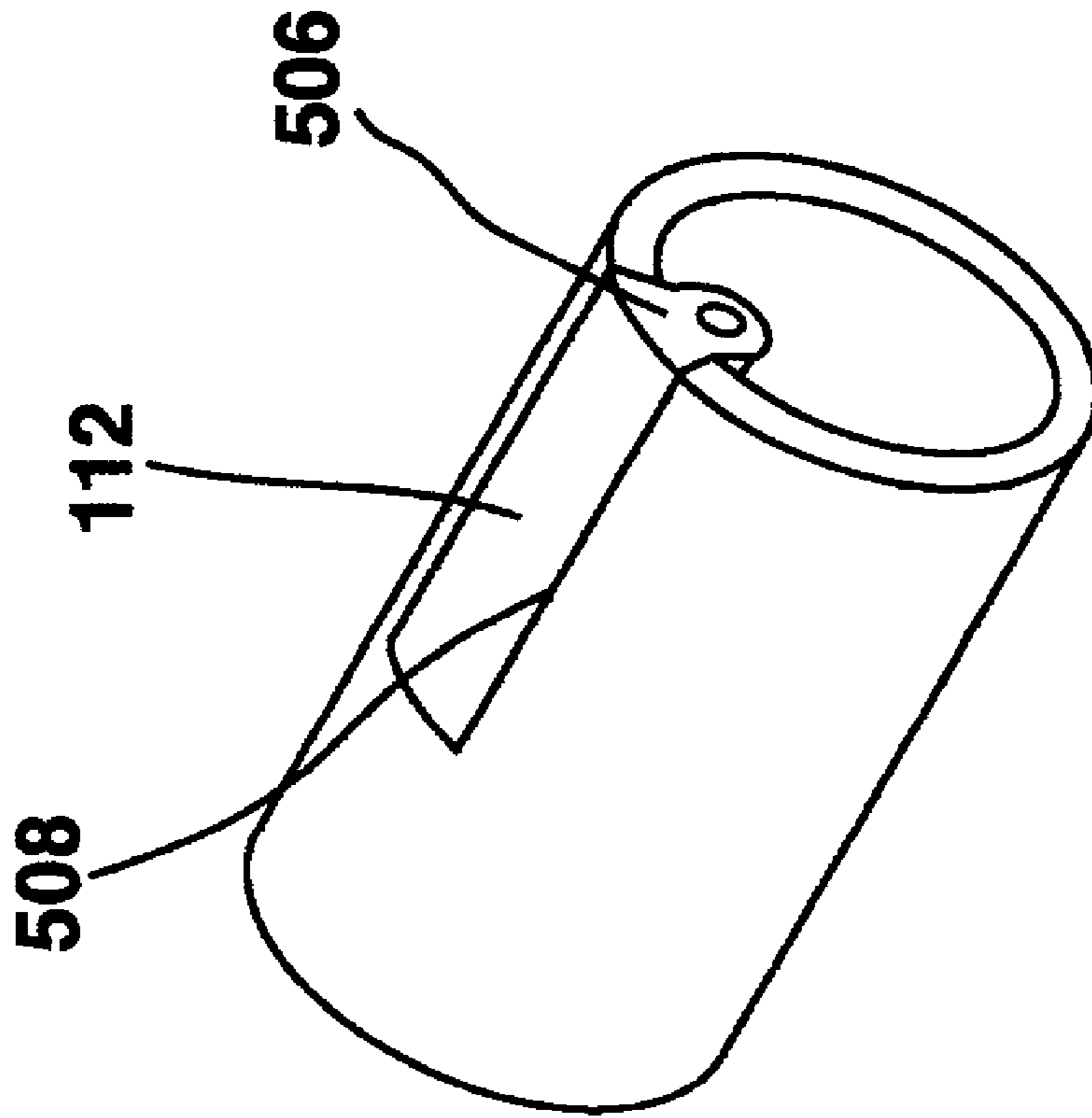


FIG. 14

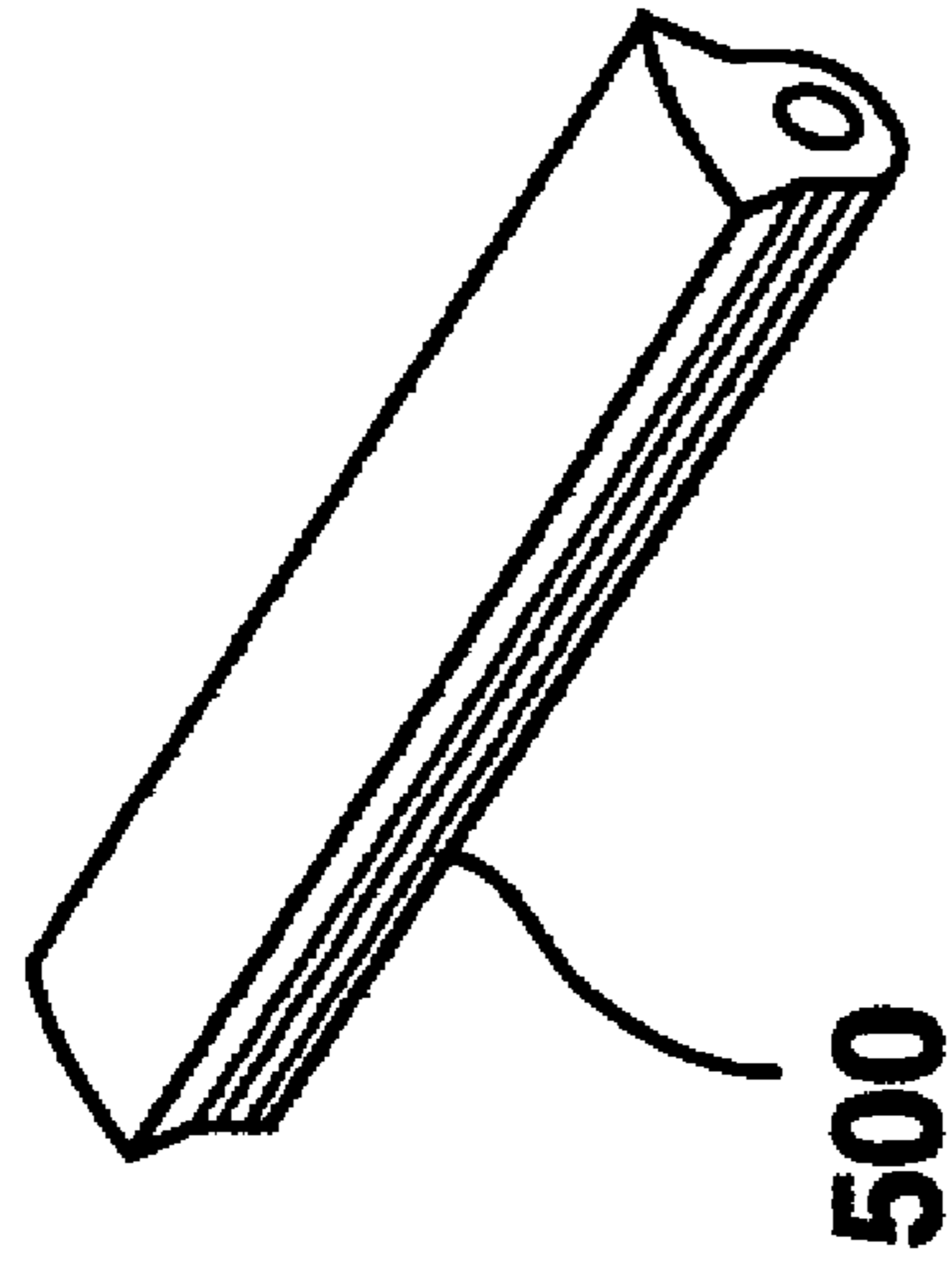


FIG. 15

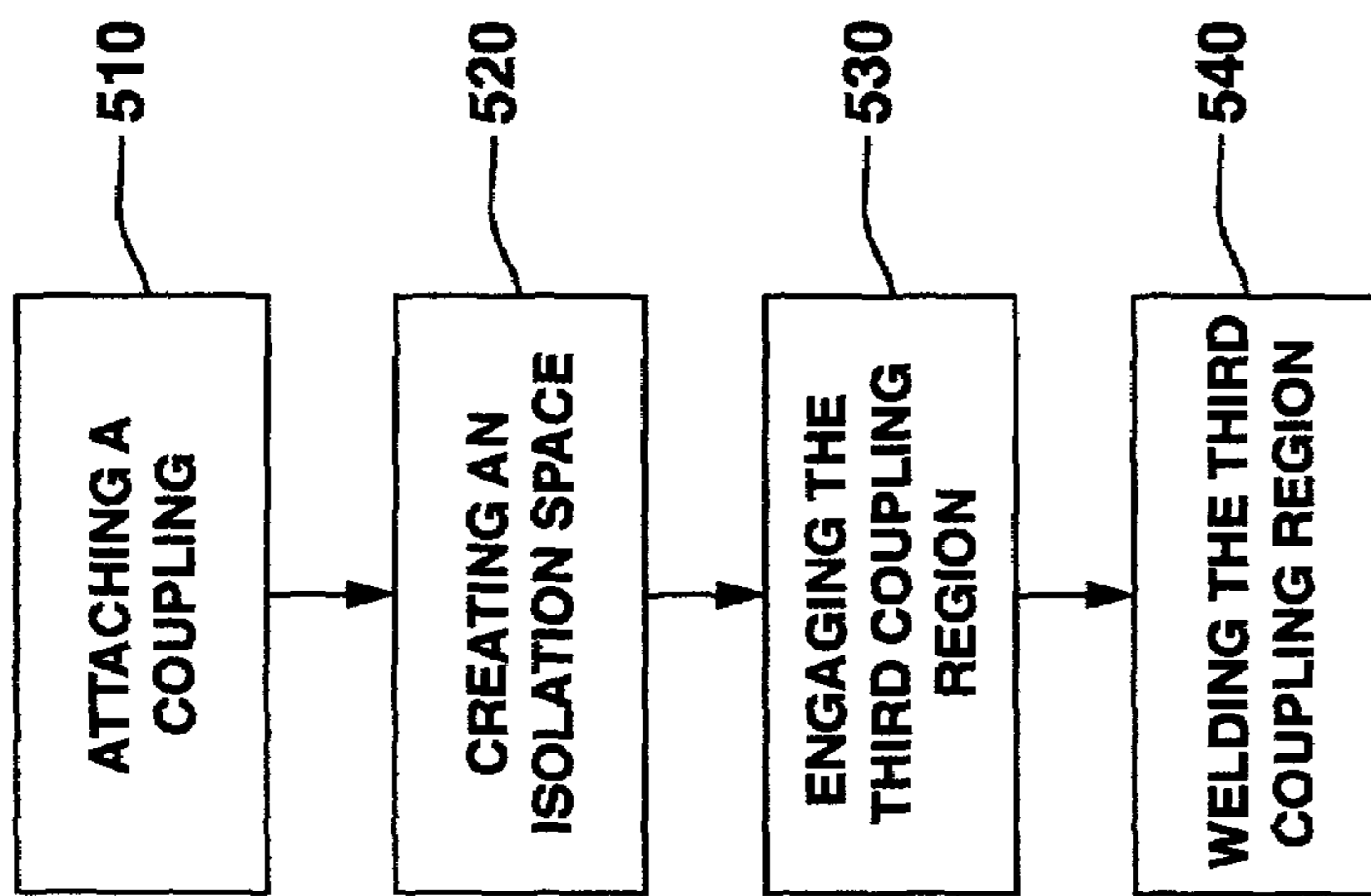


FIG. 16

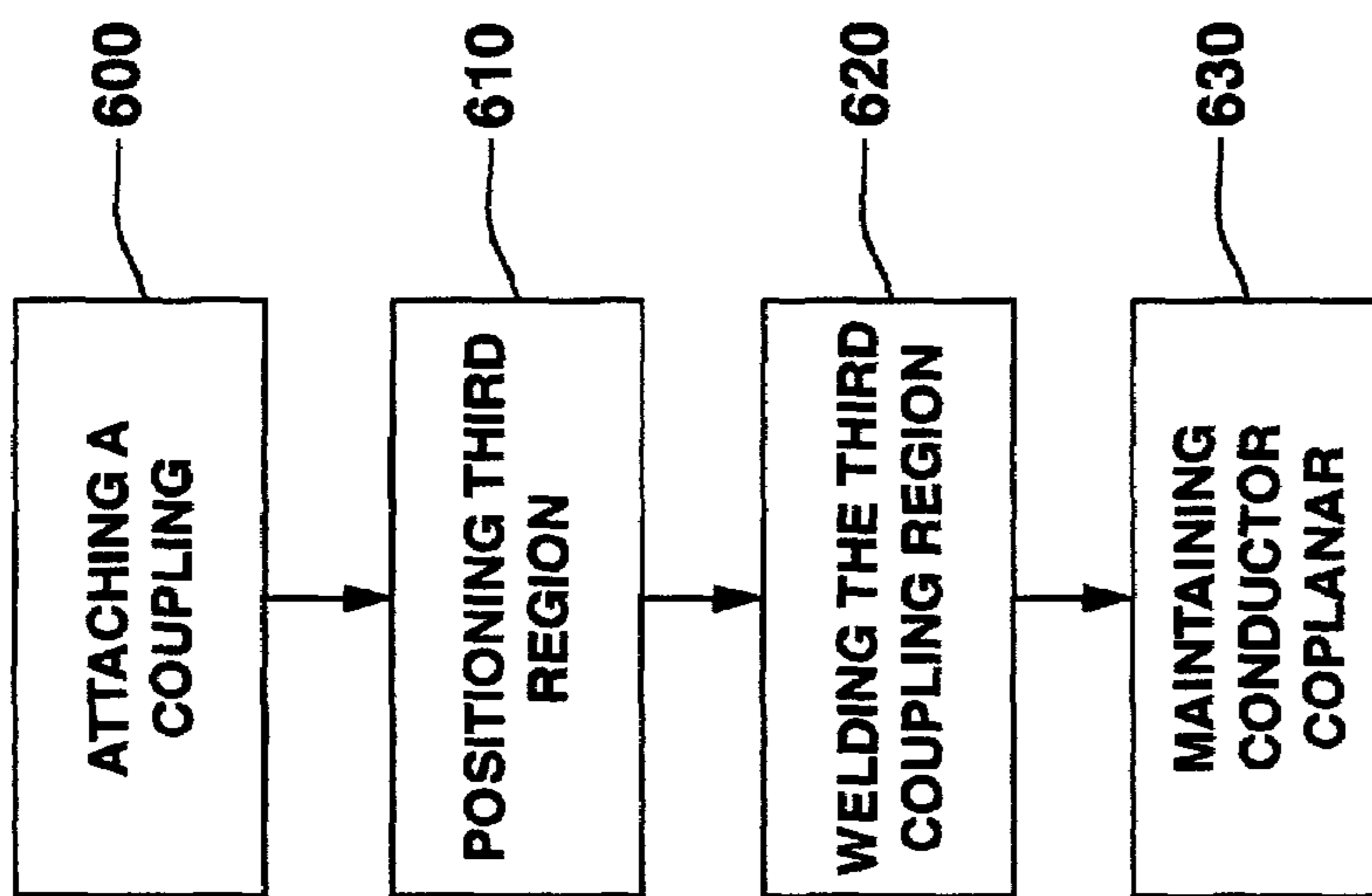


FIG. 17

IMPLANTABLE LEAD WITH ISOLATED CONTACT COUPLING

CROSS REFERENCES

This application is related to the following co-pending applications entitled “Implantable Lead With Improved Conductor Lumens” by Pardo et al. application Ser. No. 10/128,884); “Implantable Lead With Improved Stylet Lumen” by Pardo et al. application Ser. No. 10/131,559); “Implantable Lead With Improved Distal Tip” by Stolz et al. application Ser. No. 10/128,934); “Improved Stylet For An Implantable Lead” by Pardo et al. application Ser. No. 10/128,882); and, “Implantable Lead With Coplanar Contact Coupling” by Cole et al. application Ser. No. 10/131,106), which are not admitted as prior art with respect to this application by its mention in this cross reference section.

BACKGROUND OF THE INVENTION

This disclosure relates to medical devices and more particularly to an implantable lead.

The medical device industry produces a wide variety of electronic and mechanical devices for treating patient medical conditions such as pacemakers, defibrillators, neurostimulators and therapeutic substance delivery pumps. Medical devices can be configured to be surgically implanted or connected externally to the patient receiving treatment. Clinicians use medical devices alone or in combination with therapeutic substance therapies and surgery to treat patient medical conditions. For some medical conditions, medical devices provide the best and sometimes the only therapy to restore an individual to a more healthful condition and a fuller life. One type of medical device is an implantable neurological stimulation system that can be used to treat conditions such as pain, movement disorders, pelvic floor disorders, gastroparesis, and a wide variety of other medical conditions. The neurostimulation system typically includes a neurostimulator, a stimulation lead, and an extension such as shown in Medtronic, Inc. brochure “Implantable Neurostimulation System” (1998). More specifically, the neurostimulator system can be an Irel II® Model 7424 or an Irel 3® Model 7425 available from Medtronic, Inc. in Minneapolis, Minn. that can be used to treat conditions such as pain, movement disorders and pelvic floor disorders. The neurostimulator is typically connected to a stimulation lead that has one or more electrodes to deliver electrical stimulation to a specific location in the patient’s body.

Implantable leads have conductors that are connected to contacts to form electrical paths. The connection between the conductors and the contacts should have a solid mechanical connection and a low impedance electrical connection for efficient operation and reliability. Conductors manufactured from low impedance materials such as silver make forming a connection with good mechanical properties challenging because silver has substantially less tensile strength than a more common conductor material such as MP35N. Additionally, silver content in the weld joint between a conductor and contact increases the chances of separation, silver exposure to tissue, and weld corrosion during lead operation. Some previous connections directly connect the conductor to the contact but sometimes the conductor material is not ideal for forming a strong mechanical connection. Additionally, conductor material such as conductor ions can migrate from the conductor to the contact or even from the conductor into the patient. Other

previous connections use a tube crimped to the conductor that is welded to the contact. Although the tube can improve the mechanical connection, material from the conductor can still migrate from the conductor to the contact or into the patient. An example of a lead with a joined conductor and electrode is shown in U.S. Pat. No. 6,181,971 “Joining Conductor Cables And Electrodes On A Multi-Lumen Lead Body” by Doan (Jan. 30, 2001).

For the foregoing reasons, there is a need for an implantable lead with isolated contact couplings to reduce the opportunity for conductor material to migrate to the contact or into the patient.

BRIEF SUMMARY OF THE INVENTION

An implantable lead with an isolated contact connection for connecting a conductor to a contact reduces the opportunity for conductor material to migrate to a contact or into a patient. The implantable lead comprises a lead body having a proximal end and a distal end, at least one conductor, at least one contact carried on the proximal end, at least one contact carried on the distal end, at least one coupling. The lead has an exterior surface. The conductor is contained in the lead body and extends from the lead proximal end to the distal end. The conductor is electrically insulated. The contact carried on the proximal end is electrically connected to the conductor, and the contact carried on the distal end is also electrically connected to the conductor. The coupling has a conductor coupling and a contact coupling. The conductor coupling is placed over the conductor and attached to the conductor. The contact coupling exits the lead body and has a weld to connect the contact coupling to the contact. There is an isolation space created between the conductor and the contact to prevent the weld from containing conductor material.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a general environmental view for a neurostimulation system embodiment;

FIG. 2 shows a neurostimulation system embodiment;

FIG. 3 shows an implantable lead embodiment;

FIG. 4 shows an implantable lead with cross-section indication embodiment;

FIG. 5 shows a cross section of the implantable lead embodiment shown in FIG. 4;

FIG. 6 shows an implantable lead with proximal end enlargement indication embodiment;

FIG. 7 shows an enlarged cross section of the proximal end shown in FIG. 6;

FIG. 8 shows an implantable lead with distal end enlargement indication embodiment;

FIG. 9 shows an enlarged cross section of the distal end shown in FIG. 8 embodiment;

FIG. 10 shows a stylet with distal end enlargement indication embodiment;

FIG. 11 shows the enlarged distal end shown in FIG. 10 embodiment;

FIG. 12 shows an implantable lead with enlargement indication of a contact embodiment;

FIG. 13 shows a cross section of the enlarged contact embodiment;

FIG. 14 shows an isometric view of a contact and coupling embodiment;

FIG. 15 shows an isometric view of the coupling embodiment shown in FIG. 14;

FIG. 16 shows a flow chart of a method for creating an isolation space in an implantable lead contact connection embodiment; and,

FIG. 17 shows a flow chart of a method for creating a coplanar connection in an implantable lead between a conductor and a contact embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a general environmental view of an implantable neurostimulation system embodiment and FIG. 2 shows a neurostimulation system embodiment. Neurostimulation systems are used to treat conditions such as pain, movement disorders, pelvic floor disorders, gastroparesis, and a wide variety of other medical conditions. The neurostimulation system 20 includes a neurostimulator 22 such as an Irel II® Model 7424 or an Irel 3® Model 7425 available from Medtronic, Inc. in Minneapolis, Minn., a stimulation lead extension 24, and a stimulation lead 30. The neurostimulator 22 is typically implanted subcutaneously in the patient's body 18 at a location selected by the clinician. The stimulation lead 30 is typically fixed in place near the location selected by the clinician using a device such as the adjustable anchor. The implantable lead 30 can be configured as a neurological stimulation lead, a neurological sensing lead, and a combination of both as a neurological stimulation and sensing lead, a cardiac lead, and the like.

FIG. 3 shows an implantable lead embodiment. An implantable lead comprises a lead body 32, at least one conductor 34, at least two contacts 36. The lead body has a proximal end 38, a distal end 40, and an exterior surface 44. The lead body 32 can be composed of a wide variety of electrically isolative materials and configurations. Materials may include, but are not limited to, silicone rubber, polyurethane, fluoropolymers and the like. Configurations could include monolumen and multilumen lead bodies. The exterior surface 44 is composed of one or more biocompatible materials.

The conductor 34 is contained in the lead body and generally extends from the lead proximal end 38 to the distal end 40. The conductors 34 can be manufactured from a wide range of materials that are electrically conductive such as MP35N, platinum and the like. In some embodiments, the conductor 34 can comprise a plurality of wires that can be configured as braided strand wire (BSW). BSW is available in many configurations including seven wire BSW. When low impedance is desired, the core of each wire can be manufactured from a low impedance metal such as silver and the jacket can be manufactured from a material with good mechanical strength properties such as MP35N. One embodiment of conductor 34 uses seven wire BSW with a silver core and an MP35N jacket typically with a resistance of less than about 0.098 ohms/cm (3 ohms/foot) and a tensile strength greater than 5N. The conductor 34 can be electrically insulated with a fluoro-polymer such as ethylenetetrafluoroethylene with a coating thickness of approximately 0.0002 cm (0.0008 inch).

The contacts 36 includes at least one contact 36 carried on the lead distal end 40 that is electrically connected to the conductor 34 and at least one contact 36 carried on the proximal end 38 that is electrically connected to the conductor 34. The proximal contacts are typically manufactured from a material with good mechanical strength and biocompatible properties such as MP35N and the like to withstand interaction with mating devices such as an implantable neurological extension. The distal contacts are typically

manufactured from materials with good electrical and biocompatibility properties such as platinum and iridium alloys that can be configured in a mixture such as 90% platinum and 10% iridium. In some embodiments, spacers 46 are inserted between contacts 36 so the proximal end 38 and distal end 40 are substantially iso-diametric.

FIG. 4 shows an implantable lead embodiment, and FIG. 5 shows a cross section of the implantable lead in FIG. 4. An implantable lead with improved conductor lumens comprises a lead body 32, a stylet lumen 100, at least one conductor lumen 102, and at least one axial slit 42. The lead body has an internal portion 104 and an external portion 106. The stylet lumen 100 and the conductor lumen 102 are formed in the internal portion 104. The internal portion 104 is a continuous material that has a proximal end 38, distal end 40 and an outer surface that is encapsulated by the external portion 104. This structure can be extruded and its configuration can be substantially the same at any longitudinal cross section. The internal portion 104 has an outside diameter smaller than the inside diameter of the external portion 106. In some embodiments, the internal portion 104 outside diameter is approximately 0.102 cm (0.04 inch) smaller than the external portion 104 inside diameter. The internal portion 104 is fitted inside of the external portion 106. The external portion 106 exterior surface 44 typically has an outer diameter selected for the therapeutic application such as in the range from about 0.05 cm (0.02 inch) to about 0.20 cm (0.08 inch) with one embodiment having an outer diameter of about 0.127 cm (0.05 inch). The stylet lumen 100 is formed in the internal portion 104 typically in the center and sized to provide clearance between the stylet lumen 100 and the coaxially inserted stylet wire 404 in the range from about 0.00025 cm (0.0001 inch) to about 0.025 cm (0.01 inch), and in some embodiments that clearance is about 0.0038 cm (0.0015 inches).

The conductor lumen 102 is formed in the internal portion 104 and positioned near an outer surface of the internal portion 104 such that there is only a web 110 between the conductor lumen 102 and the outer surface of the internal portion 104. Some embodiments have a plurality of conductor lumens 102 such as in the range from about two to sixteen conductor lumens 102. The implantable lead embodiment shown has four conductor assembly lumens that are substantially equidistant from each other and to the centrally localized stylet lumen. The conductor lumens 102 and stylet lumen 100 geometry provides axial stability, and the centrally located stylet lumen 100 improves navigation. Each conductor lumen 102 can be configured to resemble a polygon that is not necessarily symmetrical, and each conductor lumen 102 has a diameter typically greater than about 0.0254 cm (0.01 inch). In some embodiments, the conductor lumens 102 electrically insulate each conductor 34 and physically separate each conductors 34 to facilitate identification of the conductor 34 that is appropriate for its single corresponding contact 36. The film 108 thickness between the conductor lumens 102 and the stylet lumen 100 is no less than about 0.00254 cm (0.001 inch). This film 108 is flexible enough to allow the entering stylet to slide through the lead body without penetrating through into a conductor lumen 102 or out of the lead body.

The web 110 allows an axial slit 42 to be created in the internal portion 104 distal end for a path to exist between the conductor lumen 102 and the internal portion 104 outer surface. The web 110 is no greater than 0.005 cm (0.002 inch) thick. The web 110 provides the means for a conductor lumen 102 formed inside the lead body to be positioned near the exterior surface 44 of the lead body. The axial slit 42 is

formed in the internal portion 104 distal end between the conductor lumen 102 and the outer surface of the internal portion 104. The axial slit 42 provides a temporary opening for a coupling 112 (FIG. 7) to exit the conductor lumen 102 and attach to a contact 36. The axial slit 42, when stretched 5
ajar, opens to a width of at least about 0.01 cm (0.0039 inch) to allow the coupling 112 to exit the conductor lumen 102. Once the coupling 112 is connected to the contact 36, the axial slit 42 preferably seals back.

FIG. 6 shows an implantable lead with proximal end 38 10
enlargement indication embodiment, and FIG. 7 shows an enlarged cross section of the proximal end 38 shown in FIG. 6. An implantable lead with improved stylet lumen comprises a lead body, at least two conductors 34, contacts 36, and a proximal flare 200. The lead body has a proximal end 38, a distal end 40, a stylet lumen 100, and at least two conductor lumens 102. The conductors 34 are contained in the conductor lumens 102 extending from the lead proximal end 38 to the distal end 40. The contacts 36 are carried on the distal end 40 and electrically connected to the conductors 34. Typically, conductors 34 are also carried on the proximal end 38 and electrically connected to the conductors 34.

The proximal flare 200 is formed on the lead body proximal end 38 and it has tapering walls that narrow toward a stylet opening to guide insertion of a stylet (FIG. 10) into the stylet lumen 100, and the proximal flare 200 seals the conductor lumens 102 proximal end to isolate the conductor lumens 102. The proximal flare 200 is manufactured for a non-rigid material typically similar to the lead body material. The tapering walls have a slope typically in the range from about 0.25 cm/cm to about 0.50 cm/cm. The axial length of the flare 200 is no greater than about 0.064 cm (0.025 inches). The wall thickness of the flare 200 ranges from 0.01 cm (0.004 inch), at the most proximal end, to 0.05 cm (0.019 inch), at the distal end of the flare 200. The proximal flare 200 is flexible to reduce stylet deformation during insertion or withdrawal of the stylet. During stylet insertion into the stylet lumen 100, navigation, and withdrawal, the tapered walls absorb energy and stretch to accommodate movement of the stylet to reduce stylet deformation. Also during stylet insertion into the stylet lumen 100, the proximal flare 200 substantially prevents the stylet from entering the conductor lumens 102. The flare 200 provides a progressive tactile feedback to indicate to the clinician the amount of stylet pressure being applying to the lead proximal end 38 which reduces lead/stylet damage or deformation during implant.

The proximal flare 200 seals the conductor lumens 102 proximal end to isolate the conductor lumens 102. The forming of the flare 200 places material in the conductor lumens 102 that typically extends no farther than the beginning of the conductors 34 located within the conductor lumens 102. Sealing the conductor lumens 102 minimize electrical conductance between the conductors 34, fluid migration into the lumens or other attached neurological devices, and unwanted stylet introduction into the conductor lumens 102. The proximal flare 200 is manufactured from a non-rigid material that can be the same material as the lead body. The flare 200 can be formed by inserting the proximal end 38 of the lead body into a mold that has a conical shape. This conical shape is inserted axially into the center stylet lumen 100. Heat is transferred from the conical mold to the polyurethane internal portion 104 that seals the outer lumens and creates the flare 200.

FIG. 8 shows an implantable lead with distal end 40 65
enlargement indication embodiment, and FIG. 9 shows an enlarged cross section of the distal end 40 shown in FIG. 8.

An implantable lead with an improved distal tip 300 comprises a lead body, at least two conductors 34, contacts 36, a stylet lumen 100, conductor lumens 102, and a distal tip 300. The lead body has a proximal end 38, a distal end 40, a stylet lumen 100, and at least two conductor lumens 102. The at least two conductors 34 contained in the conductor lumens 102 extending from the lead proximal end 38 to the distal end 40. The at least two contacts 36 carried on the proximal end 38 are electrically connected to the conductors 34. The at least two contacts 36 carried on the lead distal end 40 are also electrically connected to the conductors 34.

The formed distal tip 300 seals the conductor lumens 102 free from adhesive or solvents. The conductor lumens 102 closed off by the formed distal tip 300 improve electrical isolation between the conductors 34. The formed distal tip 300 penetrates the lumens 100, 102 of the lead body. The material filling reaches no further into the lumens than making contact to the enclosed conductors 34.

The distal tip 300 can be formed from the lead body by inserting into a mold; this mold has the shape of the desired distal tip 300. The distal tip 300 has a diameter approximately equal to the lead final diameter of approximately 0.127 cm (0.05 inch). The heat conducted from the mold to the lead distal tip 300, melts the surrounding material into the conductor lumen 102 and into the stylet lumen 100, completely sealing them from the outside. Sufficient material is left between the lumens 100, 102 to the outside of the lead such that substantial force would be needed to perforate, if at all, through the finally formed distal tip 300. The formed distal tip 300 is of the same material of the lead body and significantly minimizes the possibility of separation from the lead body.

The distal tip 300 is substantially symmetrical since there is no need to align a separate distal tip 300. The distal tip 300 is symmetrically formed such that it is coaxial with the lead body. Symmetry is desirable for minimized protuberances from the exterior lead surface 44, thus reducing the potential of lead body ruptures. The symmetrical formation of the distal tip 300 also reduces physical and material discontinuities in the distal tip 300 to improve the navigational sensitivity of the lead 30 during implant potentially reducing operating room time.

The distal tip 300 is a more robust stylet stop which reduces the opportunity for stylet penetration of the lead body distal end 40. The material penetrates the most distal end of the stylet lumen 100 by about 0.15 cm (0.059 inch) into the stylet lumen 100 of the lead beginning from the most distal end of the hemi-spherical distal tip 300. The force transfer required for perforation of the lead distal end 40 is significantly increased, therefore, reducing any potential of tissue damage due to an exiting stylet and reducing the potential of creating an opening in the lead which may disable electrical properties of the device.

FIG. 10 shows a stylet with stylet distal end 400 enlargement indication embodiment, and FIG. 11 shows the enlarged distal end shown in FIG. 10. An implantable lead with an improved stylet comprises a lead body, a stylet lumen 100, at least one conductor 34, contacts 36, and a stylet. The lead body has a proximal end 38, a distal end 40, an exterior surface 44, and a stylet lumen 100 contained inside the lead body. The conductor 34 is contained in the lead body and generally extends from the lead proximal end 38 to the distal end 40. The conductor 34 is electrically insulated by the lead body. There is at least one contact 36 carried on the lead proximal end 38 that is electrically connected to the conductor 34, and there is at least one

contact **36** carried on the lead distal end **40** that is electrically connected to the conductor **34**.

The stylet is composed of a stylet handle **402** that attaches to the proximal end **38** of the lead and a stylet wire **404**. The stylet wire **404** is configured for insertion into the stylet lumen **100** with a straight portion **406**, a curved portion **408**, and a ball tip **410** on the stylet distal end **400**. The straight portion of the lead has a diameter of about 0.0254 cm (0.01 inch) and has a parylene insulation of about 1.0 micron. The electrical insulation also serves as a coating that has a lower coefficient of friction than the stainless steel of the stylet wire **404**.

The curved portion of the stylet wire **404** has an angle, between the tangent of the curved portion and the straight portion that increases as the curve approaches the stylet distal end **400**. The curved portion begins at about less than 3.75 cm (1.48 inches) from the stylet distal end **400** of the stylet wire **404**. The most distal angle of the curved portion has an angle greater than about 15 degrees from the straight portion.

The tangent of the curve with respect to the straight portion of stylet increases linearly as the curve approaches the stylet distal end **400**. Once fully inserted into the lead, the stylet/lead results in a distal end angle that allows the physician to manipulate the device into the desired location over the epidural space. The continuous and incremental curve of the lead distal tip **300** aids the physician to guide the lead past anatomical obstructions, that would otherwise, hinder the ease of introduction of the lead to its designated location for stimulation.

The ball tip **410** is spherical and has a diameter that is greater than the stylet diameter and is no greater than the stylet lumen **100** inner diameter. The ball tip **410** is configured to ease insertion of the stylet wire **404** through the stylet lumen **100** to the stylet distal end **400**.

The ball tip **410** functions by stretching the lumen where the stylet wire **404** is inserted to ease insertion of the remaining portion of the stylet wire **404**. In addition, the ball tip **410** reduces abrasion to the stylet lumen **100** to reduce the risk of the stylet wire **404** protruding into the adjacent conductor lumens **102** or out of the exterior surface **44** of the lead body.

FIG. **12** shows an implantable lead with contact **36** enlargement indication, and FIG. **13** shows a cross section of an enlarged contact **36** embodiment. The coupling **112** has a conductor coupling **500** and a contact coupling **502**. The conductor coupling **500** and the contact coupling **502** are manufactured from a material with good mechanical and electrical properties such as MP35N and the like. The conductor coupling **500** is placed over the conductor **34** and attached to the conductor **34** mechanically. The contact coupling **502** exits the lead body and has a weld **504** to connect the contact coupling **502** to the contact **36**. The weld **504**, such as a laser weld, can be performed substantially on the contact **36** exterior surface **44** for ease of manufacturing. The weld **504** is performed such that the weld **504** pool is typically contained within the contact **36** perimeter. In addition, the weld **504** height is controlled to be less than about 0.0127 cm (0.005 inch), so interaction with other devices is facilitated. Each contact **36** has a contact slot **508** opening that in some embodiment is in the range from about 0.0127 cm (0.005 inch) to about 0.0381 cm (0.015 inch) in width and at least about 0.0508 cm (0.020 inch) in length. In other embodiments, the contact slot **508** can extend the entire length of the contact **36**.

An isolation space **506** is created between the conductor **34** and the contact **36** to prevent directly welding the

conductor **34** to the contact **36**. The isolation space **506** separates the conductor **34** from the weld **504** to substantially prevent the conductor **34** from contacting the weld **504**. The isolation space **506** is necessary since silver is not wanted in the weld **504** pool because silver potentially weakens the strength and integrity of a weld **504**. In addition, it is desirable to avoid having silver contact the outside surface of the lead to avoid any direct contact with tissue. Although silver contact with tissue is not considered harmful, the separation serves as an additional precaution. The isolation space **506** is greater than about 0.05 cm (0.02 inch). The isolation space **506** serves as a means for isolation created between the conductor **34** and the contact **36** to prevent directly welding the conductor **34** to the contact **36**. In some embodiments, the isolation space can include a fill material such as epoxy.

FIG. **14** shows an isometric view of a contact **36** and coupling **112** embodiment, and FIG. **15** shows an isometric view of the coupling **112** embodiment shown in FIG. **14**. In this embodiment, the isolation space **506** is provided by the specific geometry of the contact coupling **502** and more specifically the non-welded material between the conductor **34** and the weld **504** to the contact **36**. The non-welded material is sized appropriately for the dimensions of the lead such as greater than about 0.005 cm (0.002 inches). In this embodiment, the interface between the outer surface of the contact **36** and the other surface of the coupling **500** can be continuously welded along selected sides of the interface or intermittently welded along the interface.

FIG. **16** shows a flow chart of a method for creating an isolation space **506** in an implantable lead contact connection embodiment. The method for creating an isolation space **506** comprises the following elements. A coupling **112** is attached **510** to a conductor **34** so that the conductor **34** extends into a first coupling region **500** of the coupling **112**. The coupling **112** has a second coupling region **506** that is adjacent to the first coupling region **500** and a third coupling region **502** adjacent to the second coupling region **506**. An isolation space **506** is created **520** and formed by the second coupling region **506**. The isolation space **506** is void of the conductor **34**. The third coupling region **502** is engaged **530** into a contact slot **508** formed in a contact **36**. The third coupling region **502** is welded **540** to the contact **36** creating a contact weld **504**.

In the coupling **112** embodiment shown in FIG. **13**, the method for creating an isolation space **506** in an implantable lead contact connection is performed as follows. A coupling **112** is attached to a conductor **34** distal end so that a first coupling region **500**, a second coupling region **506**, and a third coupling region **502** are formed. The first coupling region **500** is mechanically attached to the conductor **34** in a crimping process that substantially reduces the diameter of the first coupling region **500** such that it engages the conductor **34** firmly. During mechanical attachment, the crimping force is adjusted to obtain an adequate pull strength while avoiding undesired damage/deformation to the wire **404**. The conductor **34** distal end extends into the first coupling region **500** of the coupling **112**. The second coupling region **506** is distal to the first coupling region **500**, and the third coupling region **502** is distal to the second coupling region **506**. The first region can be about 0.10 cm (0.04 inch) long, the second region can be about 0.05 cm (0.02 inch) and the third region can be about 0.076 cm (0.03 inch) long. An isolation space **506** is created and formed by the second coupling region **506**, with the isolation space **506**

void of the conductor 34. The isolation space 506 is void of the conductor 34 so that the weld 504 encompasses the third region and the contact 36.

The assembly consisting of the conductor 34 and the attached couplings 112 on either end can be fed through a lead body. The placement of the assembly is such that the proximal coupling is on the proximal end 38 of the lead body and the distal coupling is on the distal end of the lead body. The contact 36 with a contact slot 508 is placed on the lead body distal end. The contact slot 508 width is slightly less than the diameter of the third coupling region 502. The length of the contact slot 508 is greater than the diameter of the coupling 112 to allow for placement anywhere along its length. The contact slot 508 assists in holding the coupling 112 in place prior to welding the third region to the contact 36.

An axial slit 42 is created in the lead body distal end. The axial slit 42 is long enough such that it allows for an opening of at least the diameter of the third coupling region 502. The coupling 112 attached to the conductor 34 is exited through the axial slit 42 in the lead body distal end. The axial slit 42 permits the coupling 112 to pass through to mate to the contact 36 with the minimum amount of movement of the conductor 34 assembly within the lead body. Also, the axial slit 42 allows for a minimum sized path to exist between the conductor lumen 102 and the contact 36. In the creation of the axial slit 42, material is not removed, only a cut is made such that it allows the passage of the coupling 112 from the conductor lumen 102 to the contact slot 508 area. The cut is created with a sharp razor and extends for about 0.076 cm (0.030 inch). It is made approximately under the location where the contact 36 will be placed over and mate with the coupling 112.

The third coupling region 502 is bent in the range from about 85 degrees to about 120 degrees in relation to the longitudinal axis of the conductor 34. The bend can be made with a tool the size of a wrench that creates a bend beginning at the same location of the coupling 112, roughly 0.076 cm (0.03 inch) distally. The third coupling region 502 distal end is formed into a contact coupling 502 that is complimentary to a contact slot 508. The diameter of the third coupling region 502 is deformed such that it closes the conductor 34 void opening of the third coupling region 502. Also, the formed final geometry of the third region of the coupling 502 has an interference fit with the contact slot 508.

The contact coupling 502 is engaged into the contact slot 508. The entire perimeter and cross section of the third region 502 is placed within the open area of the contact slot 508. At this point the third coupling region 502 is held by the contact slot 508 and is ready for a more secure attachment. The contact coupling 502 is welded to the contact slot 508. The weld 504 can be created with a laser welder that heats up the slot 508 region of the contact 36 and the third region of the coupling to the point where they become an alloy. The weld 504 bump created is no greater than about 0.013 cm (0.005 inch) over the surface of the contact 36. Also, the weld 504 bridges over each end of the slot 508 to provide mechanical integrity. The inner void of the third coupling region 502 distal end is sealed by the weld 504. The weld 504 surface area extends over the third region 502 of the coupling and the proximate perimeter of the contact slot 508. The weld 504 material creates a closed section in the third region 502 opening creating a closed section of the coupling distal end (third coupling region 502).

FIG. 12 shows an implantable lead with contact enlargement indication, and FIG. 13 shows a cross section of an enlarged contact embodiment. An implantable lead with

coplanar contact connection comprises a lead body having a proximal end 38 and a distal end 40, at least one conductor 34, at least one contact 36 carried on the proximal end 38, at least one contact 36 carried on the distal end 40, and at least one coupling 112. The lead body 32 has an exterior surface 44. The conductor 34 is contained in the lead body 32 and extends generally from the lead proximal end 38 to the distal end 40. The conductor 34 is electrically insulated. There is at least one contact 36 carried on the proximal end 38 that is electrically connected to the conductor 34, and at least one contact 36 carried on the distal end 40 that is electrically connected to the conductor 34. The coupling 112 has a conductor coupling 500 and a contact coupling 502. The conductor coupling 500 is placed over the conductor 34 and attached to the conductor 34. The contact coupling 502 exits the lead body and is welded to connect the contact coupling 502 to the contact 36 carried on the distal end 40. The contact coupling 502 is further configured to exit the conductor lumen 102 and mate with the contact 36 while retaining the conductor 34 coplanar to the contact 36. The coplanar relationship between the conductor 34 and the contact 36 is such that the longitudinal axis of the conductor 34 is maintained substantially parallel to the longitudinal axis of the contact 36.

In some embodiments such as shown in FIG. 13, the contact coupling 502 can be bent to exit the conductor lumen 102 and mate with the contact 36 while maintaining the conductor 34 coplanar to the contact 36. The contact coupling 502 bend serves as a means for orienting the contact coupling 502 to exit the conductor lumen 102 and mate with the contact 36. The contact coupling 502 can be bent in the range from about 85 degrees to about 120 degrees in relation to the conductor 34. In other embodiments such as shown in FIGS. 14 and 15, the geometry of the contact coupling 502 is such that the contact coupling 502 does not require mechanical deformation of the second region 506 or third region 502.

The conductors 34 are contained within the lumens throughout the lead body, such that it does not exit the lead at any point. The conductor 34 is parallel to the lead body in its entire length. This allows the conductor 34 to not directly contact the outside surface of the lead or the surrounding tissue. Conductor 34 stresses are significantly reduced by not allowing the conductor 34 to have a bending moment. Lead reliability is improved as a result from this coplanar conductor 34 to contact 36 attachment.

FIG. 17 shows a flow chart of a method for creating a coplanar connection in an implantable lead between a conductor 34 and a contact 36 embodiment. The method for creating a coplanar connection in an implantable lead between a conductor 34 and a contact 36 comprises the following elements. A coupling 112 is attached 600 to a conductor 34 distal end, so the conductor 34 distal end extends into a first coupling region 500 of the coupling. The coupling 112 has a second coupling region 506 adjacent to the first coupling region 500. The coupling second region 506 is positioned 610 in a conductor lumen 102 adjacent 620 to a contact 36. The second region 506 is welded 62 to the contact 36 creating a contact weld 504. The conductor 34 distal end is maintained in a coplanar relation 630 to the contact 36.

Thus, embodiments of the implantable lead with isolated contact coupling 502 and method are disclosed to improve isolation between the contact 36 and conductor 34. One skilled in the art will appreciate that the present invention can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for pur-

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poses of illustration and not limitation, and the present invention is limited only by the claims that follow

What is claimed is:

1. An implantable lead with an isolated contact connection, comprising:

a lead body having a proximal end, a distal end, and an exterior surface;

at least one conductor contained in the lead body extending from the lead proximal end to the distal end, the conductor being electrically insulated;

at least one contact carried on the proximal end and electrically connected to the conductor;

at least one contact carried on the lead distal end and electrically connected to the conductor; and,

at least one coupling having a conductor coupling, an isolation space, and a contact coupling, the conductor coupling being placed over the conductor and attached to the conductor, the isolation space being void of the conductor and extending axially from the conductor coupling, and the contact coupling extending radially outward from the isolation space, exiting the lead body and having a weld to connect the contact coupling to a contact slot formed in the contact,

wherein the isolation space is created between the conductor and the contact to prevent directly welding the conductor to the contact, the isolation space is a hollow portion of the coupling,

wherein the hollow portion of the coupling is at least partially filled with a non-conductive fill material.

2. The implantable lead as in claim 1 wherein the isolation space separates the conductor from the weld to substantially prevent the conductor from contacting the weld.

3. The implantable lead as in claim 1 wherein the isolation space is configured to reduce communication between tissue and the conductor.

4. The implantable lead as in claim 1 wherein the isolation space reduces ion migration from the conductor outside of the lead body.

5. The implantable lead as in claim 1 wherein the conductor coupling is attached to the conductor by crimping.

6. The implantable lead as in claim 1 wherein the weld is performed substantially on the contact exterior surface for ease of manufacturing.

7. The implantable lead as in claim 1 wherein the isolation space between the conductor and the contact is greater than about 0.1 centimeters.

8. The implantable lead of claim 1 wherein the at least one distal end contact is a ring electrode contact.

9. An implantable lead with an isolated contact connection, comprising: a lead body having a proximal end, a distal end, and an exterior surface; at least one conductor contained in the lead body extending from the lead proximal end to the distal end, the conductor being electrically insulated; at least one ring electrode contact carried on the proximal end and electrically connected to the conductor; at least one ring electrode contact carried on the lead distal end and electrically connected to the conductor; and, at least one coupling having a conductor coupling and a contact coupling, the conductor coupling being placed over the conductor and attached to the conductor and the contact cou-

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pling exiting the lead body and having a weld to connect the contact coupling to a contact slot formed in the ring electrode contact, means for isolation void of the conductor created between the conductor and the ring electrode contact to prevent directly welding the conductor to the ring electrode contact, the isolation void is a hollow portion of the coupling, wherein the hollow portion of the coupling is at least partially filled with a non-conductive fill material.

10. An isolated contact connection for an implantable lead, comprising:

a connector body;

a first region in the connector body, the first region configured for receiving a conductor end;

a second region adjacent to the first region; and,

a third region adjacent to the second region, the third region configured for being welded to a contact slot formed in a ring electrode contact to create a contact weld,

wherein the second region is void of the conductor and provides physical isolation between the first region and the third region to isolate the contact weld from the conductor, the second region being a hollow portion of the coupling and at least partially filled with a non-conductive material.

11. The isolated contact connection as in claim 10 wherein the second region separates the conductor from the weld to substantially prevent the conductor from contacting the weld.

12. The isolated contact connection as in claim 10 wherein the second region is configured to reduce communication between tissue and the conductor.

13. The isolated contact connection as in claim 10 wherein the second region reduces ion migration from the conductor outside of the lead body.

14. The isolated contact connection as in claim 10 wherein the first region is attached to the conductor by crimping.

15. The isolated contact connection as in claim 10 wherein the weld is performed substantially on the contact exterior surface for ease of manufacturing.

16. The isolated contact connection as in claim 10 wherein the second region between the first region and the third region is greater than about 0.1 centimeters.

17. A method for creating an isolation space in an implantable lead electrode connection, comprising:

attaching a coupling to a conductor so that the conductor extends into a first coupling region of the coupling, the coupling having a second coupling region adjacent to the first coupling region and a third coupling region adjacent to the second coupling region;

creating an isolation space formed by the second coupling region, the isolation space void of the conductor;

engaging the third coupling region into a contact slot formed in a ring electrode contact; and,

welding the third coupling region to the ring electrode contact creating a contact weld.

18. The method as in claim 17 further comprising isolating the conductor from the contact weld.